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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,756	03/24/2001	Bruce J. Mayer	883933.0062 (UCON-154)	4784

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MCCARTER & ENGLISH LLP  
CITYPLACE I  
185 ASYLUM STREET  
HARTFORD, CT 06103

EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/816,756

**Applicant(s)**

MAYER, BRUCE J.

**Examiner**

T. D. Wessendorf

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Status of Claims***

Claims 28-29 have been cancelled in the 7/21/2000 Amendment. Claims 30-34 have been added.

Claims 31 and 32 do not have a status identifier.

Claims 1-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 30-34 are under examination.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Src as the modular protein binding domain (MPBD), does not reasonably provide enablement for a method employing any kind of modular protein binding domain for reasons advanced in the last Office action.

***Response to Arguments***

Applicant argues that prior art reference, Michnick et al and the other prior art have been provided to skilled in the art in practicing the techniques without having to resort to undue experimentation. Yet admits that Michnick is different from the objective of the instant invention. Applicant's lengthy arguments with respect to Michnick are unclear. It is well settled that each case is treated on its own merits. Attention is drawn to page 5, lines 18- 27 which states that "....when the WIN-ZIP A1 fusion is **the Src tyrosine kinase**, a co-expressed WIN-ZIP B1 fusion is specifically phosphorylated on tyrosine(hereinafter, tyr) by Src (but is not phosphorylated to nearly the same extent if either of the two proteins does not bear the WIN-ZIP segment).

Applicant admits that in spite of the entirely different and distinct mechanism, protein and protein fragments ZIP A and ZIP B are overlapping and there are known by virtue of their having been described in publications available to the art.

Applicant further argues that a patent need not teach and preferably omits what is well known in the art.

In response, the numerous contradictory arguments provided by applicants made it confusing as to what is actually well known in the art. As argued the Michnick reference is entirely

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different and distinct mechanism from the instant invention. If the argued mechanism is the method hence, it is not clear as to just what is actually known to the skilled artisan.

Applicant states at page 4, paragraph 4 of the instant Remarks, the instant invention is drawn to a functional interaction trap (FIT) for the protein interaction of ZIP A and ZIP B. At the time of applicant's invention, the prior art specifically the Hurst (Protein Profile) cited in the last Office action provides the high unpredictability in the art. Hurst at page 106, col. 2, states that MPBD (i.e., transcription factor) show different activities depending which other protein it is dimerized to, as illustrated by the **complicated regulatory circuit of Jun, JunB, ATF3 and Fos**. These factors may repress depending on the context of their promoter binding site. Other bZIP proteins have different splice variants which demonstrate different activities from one another. **These activities of bZIP proteins are very varied**. Consequently, the role of the leucine zipper as a generalized protein-protein interaction domain must be investigated very carefully for each proteins (page 109, col. 2). To date sequences of a mammalian gene e.g., chicken or mouse have not been completed but have been considered as distinct genes at the present time. Because of unpredictability in the art as discussed by Hurst, one would have not deemed applicants'

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disclosure as enabling for the broad claimed method. (All emphasis added).

Applicant states that claim 32 has been drafted to the examiner's suggestion in the last Office action.

In reply, claim 32 depends on cancelled claim 28. Furthermore, the enablement issue is drawn to the broad claim 30 and not to the species as recited in claim 32.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

New claims 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 31 and 32 depend on cancelled claim 28.

B. Non-sequitur for "the first dimerization domain" in claim 30 from the preceding statement. It is not clear whether this is the same or different from the preceding "coil-coil heterodimerization domain". Step c) and step d) are confusing. It is not clear whether step c) is used as a control for step d)

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since step d) does not recite the measuring changes in relation to the control.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

New claims 30-34 are rejected under 35 U.S.C. 103(a) as being obvious over Michnick et al (US 6,270,964) or applicants' disclosure of known prior art [page 9, lines 12-17 of the instant disclosure.] for reasons set forth in the last Office action.

***Response to Arguments***

Applicant states that the applicant recites the FIT assay depends on a protein binding interface consisting of two engineered protein segments, coiled-coil heterodimerization segments, each fused in-frame to one of two proteins. Only when both modified proteins are expressed in the same cell will the two proteins bind each other, and the unique biological consequences of the interaction be assessed. Since the fusion proteins of the present invention act positively, namely by

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actually interacting, one can look for generation a function instead of loss of function for the complex. In this connection to provide disclosure, Micnick is referenced and specifically high affinity coiled-coil heterodimerization domains of the present invention are the WIN-ZIP coiled-coiled heterodimerization leucine zippers, such as those described by Michnick. It is further argued that Michnick has used his assay to teach the consequences of the interaction of the proteins fused to ZIP A and ZIP B respectively and not the consequences of the interaction of ZIP A with B i.e., the uses ZIP A and ZIP B as a component of a completely new assay for the functional consequences of protein interaction.

In response there appears to be no difference in the assay between Michnick and the instant invention except for the components used in the assay.

[As stated, incorporation of claim 32 and 34 to the independent claim will render the claim allowable].

#### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

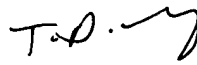
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw